producing an electrical current through a portion of the animal, if the level of the analyte exceeds a threshold amount, to warn the animal, the electrical current is produced by applying a potential between two of the conductive traces.

Remarks

This is in response to the Office Action dated November 22, 1999. Claim 118 has been amended. Claims 1, 2, 4–58, 65–78, 81–84, 92–122, and 127 are presently pending in this application. The Applicants thank the Examiner for indicating that claims 35–38, 70, 71, 112–117, 122, and 127 are allowed and that claims 1, 2, 4–9, 14–19, 24, 25, 31–34, 39–53, 55–58, 65–69, 72, 73, 82, 84, 95–99, 102, 106, 110, 111, and 121 are allowable if rewritten as independent claims.

Rejection under 35 U.S.C. §102 in view of Guilbeau

Claims 104, 105, 107, 108, and 118–120 were rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 4,935,345 to Guilbeau et al. (hereinafter "Guilbeau"). The Applicants traverse these rejections for the following reasons.

Guilbeau discloses an implantable microelectronic sensor that incorporates a thin film thermopile. Guilbeau does not disclose an electrochemical sensor. The sensor of Guilbeau measures heat generated or removed in response to a reaction of an analyte catalyzed by, for example, an enzyme. The sensor includes a number of thermocouple junctions that are created by the intersection of two dissimilar metal films. These metal films are covered by a passivation layer that physically and electrically isolates the films from the solution containing the analyte. (See Column 8, lines 23–32.) A layer containing a catalyst or enzyme is deposited over the passivation layer. In operation, the catalyst or enzyme catalyzes a reaction of an analyte. The reaction is exothermic or endothermic, which causes a change in temperature near the sensor. The thermocouple junctions respond to the change in temperature and provide a measurable signal for the device.

In contrast to the Guilbeau sensor, the claims 104, 105, 107, 108, and 118–120 recite an electrochemical sensor. In operation, an electrochemical sensor causes the electrolysis of an analyte by transfer of electrons between an electrode and the analyte (optionally, via one or more electron transfer agents, such as a redox mediator or

enzyme). The Guilbeau sensor is not an electrochemical sensor because there is no flow of electrons between an electrode and the analyte; in fact, the metal films of the Guilbeau sensor are electically insulated from the analyte–containing solution to prevent the flow of electrons. For at least this reason, claims 104, 105, 107, 108, and 118–120 are patentable over Guilbeau. Accordingly, the Applicants request withdrawal of this rejection.

Rejections under 35 U.S.C. §102 and §103 in view of Hill

Claims 81 and 83 were rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,509,410 to Hill et al. (hereinafter "Hill"). Claims 92–94, 22, 23, 26–30, 100, and 101 were rejected under 35 U.S.C. §103(a) as being unpatentable over Hill. The Applicants traverse these rejections for the following reasons.

Hill discloses a strip electrode that can be used to determine a concentration of an analyte, such as glucose. The strip electrode of Hill includes an enzyme capable of catalyzing a reaction of the analyte and an electron mediator for transferring electrons between the electrode and the analyte. In operation, the strip electrode detects the amount of analyte by determining the current generated by electrolysis of the analyte.

In contrast, claims 81 and 83 recite an electrochemical sensor that is responsive to the change in level of a second compound (e.g., oxygen or hydrogen peroxide) resulting from an enzyme–catalyzed reaction of an analyte (e.g., glucose). Such electrochemical sensor are described in the Applicants' specification at, for example, page 27, line 27 to page 29, line 11. Hill does not teach or suggest this type of electrochemical sensor, because the strip electrodes of Hill detect the analyte concentration by direct measurement of the analyte and not by measurement of the amount of a second compound which changes in response to a reaction of the analyte. In Hill, the amounts of the electron mediator and enzyme (which transfer electrons between the analyte and the electrode) remain constant during the reaction. In the Applicants' claims, an amount of a second compound is changed (e.g., the second compound is removed or generated) due to the reaction of the analyte and that second compound is subsequently electrolyzed at the working electrode. The change in the amount of the second compound is related to the amount of the analyte. Because Hill does not teach or suggest this type of electrochemical sensor, claims 81 and 83 are patentable over Hill. Accordingly, the Applicants request the withdrawal of this rejection.

Claims 92–94, 22, 23, 26–30, 100, and 101 were asserted as obvious in view Hill because the size limitation recited in the claims was deemed an engineering choice. The size of the electrode, however, determines, at least in part, the magnitude of the signal received for a given analyte concentration. As electrode size becomes smaller, the signal generated at the electrode also becomes smaller. Thus, the size of a very small electrode, such as the recited 150 μm electrodes, is not a matter of engineering choice. The electrodes can not be made arbitrarily small. The Applicants have developed electrodes that are significantly smaller than those previously disclosed. There is no teaching or suggestion in Hill that the electrodes can be made this small or that a measurable signal would be obtained using such small electrodes. For at least this reason, claims 92–94, 22, 23, 26–30, 100, and 101 are patentable over Hill. The Applicants request withdrawal of this rejection.

Rejections under 35 U.S.C. §103 in view of Guilbeau and Hill

Claims 103, 10–13, 20, 21, 54, and 74–78 were rejected under 35 U.S.C. §103(a) as being unpatentable over Hill in view of Guilbeau. Claim 109 was rejected under 35 U.S.C. §103(a) as being unpatentable over Guilbeau in view of Hill. The Applicants traverse these rejections for the following reasons.

As indicated above, Guilbeau does not teach an electrochemical sensor and, therefore, there is no motivation for one skilled in the art to look to Guilbeau for modifications to Hill. Guilbeau presents an alternative to an electrochemical sensor and has different design and technical considerations. Because Guilbeau does not disclose an electrochemical sensor, there is no disclosure in Guilbeau that can direct one skilled in the art to modify the Hill strip electrodes to make them subcutaneously implantable, as recited in claim 103. For at least this reason, claims 103 and 109 (and claims 10–13, 20, 21, 54, and 74–78 which depend from claim 103) are patentable over the cited references, alone or in combination. Moreover, because Guilbeau does not disclose an electrochemical sensor, there is no basis for the rejection of claim 109, which recites an electrochemical sensor. Accordingly, the Applicants request the withdrawal of these rejections.

Conclusion

In view of the amendments to the claims and the arguments presented herein, the Applicant respectfully submits that each of the presently pending claims (claims 1, 2, 4–58, 65–78, 81–84, 92–122, and 127) is in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicants' representative at the below–listed telephone number, if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted,

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